

REMARKS

Claims 1-12 and 14 are all the claims pending in the application.

I. RESPONSE TO REJECTION UNDER 35 U.S.C. § 102

Referring to pages 2 and 3 of the Office Action, Claims 1, 5, 7, 9-10, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2001/0012853 (“Bissett”).

Applicants respectfully traverse.

In the Amendment filed March 5, 2007, Applicants amended the independent claims to delete therefrom the recitation “or a derivative thereof” as used in connection with the recited component L-cysteine. Thus, for example, Claim 1 is presently directed to a composition which comprises (i) tranexamic acid or a salt thereof and (ii) L-cysteine or a salt thereof.

For anticipation under 35 U.S.C. § 102, the identical invention must be shown in as complete detail as is contained in the claim. With respect to each of the presently rejected claims, Bissett does not disclose the claimed subject matter as is required for an anticipation under §102. For example, the only disclosure contained in Bissett concerning cysteine is the disclosure at paragraph [0048] of “N-acetyl-L-cysteine and derivatives thereof.” N-acetyl-L-cysteine is itself a derivative of L-cysteine. Thus, the disclosure at paragraph [0048] of “N-acetyl-L-cysteine and derivatives thereof” does not disclose the “L-cysteine or a salt thereof” recited in the presently rejected claims.

In addition, Bissett does not disclose what specific compounds are included in “N-acetyl-L-cysteine and a derivative thereof.” The term “derivative” means “[s]pecifically, a chemical compound that may be produced from another compound of similar structure in one or more steps, as in replacement of H by alkyl, acyl, amino group, etc.” (*cf.* the reference Stedman's Medical Dictionary 25th edition, p. 417, left column, copies of the relevant pages of which Applicants are submitting herewith). Accordingly, L-cysteine is not regarded as a derivative of

N-acetyl-L-cysteine. Thus, Bissett does not disclose the subject matter of Claim 1 of the present application.

Reconsideration and withdrawal of the present §102 anticipation rejection is requested.

II. RESPONSE TO REJECTION UNDER 35 U.S.C. § 102

Referring to pages 3 and 4 of the Office Action, Claims 1, 3, 5, 7, 9-10, 12, and 14 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0137077 (“Ancira”).

Applicants respectfully traverse. Ancira does not disclose the subject matter of the presently rejected claims in the manner that is required for an anticipation under §102.

In this regard, the examiner’s position is “that the presence or absence of working examples does not render the claims not anticipated by the reference,” and that “Ancira discloses the same composition as the instant claims.”

Applicants respectfully disagree. Ancira does not show the identical subject matter, in as complete detail, as is contained in the presently rejected claims, and as is required for an anticipation under §102.

For the subject matter of the presently rejected independent claims, the examiner is relying on paragraph [0034] of Ancira. Paragraph [0034] of Ancira discloses a composition which “may comprise at least one melanin inhibitor.” Paragraph [0034] proceeds to describe over fifty (50) melanin inhibitors. The possible number of combinations of compositions comprising two or more melanin inhibitors described at paragraph [0034] of Ancira is at least in the hundreds, and most likely in the thousands.

Most importantly, Ancira at paragraph [0034] (or elsewhere) does not specifically direct the reader to a composition containing (i) tranexamic acid or a salt thereof and (ii) L-cysteine or a salt thereof, from among the hundreds or thousands of possible combinations described. Ancira does not specifically name a composition containing (i) tranexamic acid or a salt thereof and (ii) L-cysteine or a salt thereof. There is no reasonable basis for one to assume that one of

ordinary skill in the art would specifically select a composition containing (i) tranexamic acid or a salt thereof and (ii) L-cysteine or a salt thereof, from among the hundreds or thousands of possible combinations described at paragraph [0034] of Ancira.

Reconsideration and withdrawal of the present §102 anticipation rejection is requested.

III. RESPONSE TO REJECTIONS UNDER 35 U.S.C. § 103

Referring to pages 5-7 of the Office Action:

Claims 2-4, 6, and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bissett;

Claims 2, 4, 6, and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ancira; and

Claims 1-4 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,974,833 (“Rath”).

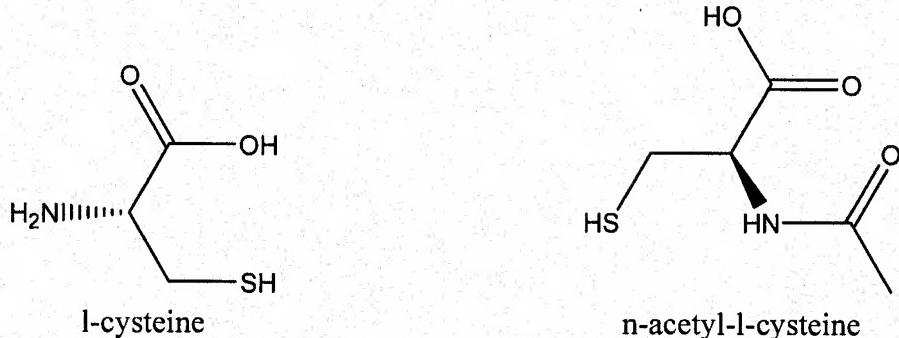
Applicants respectfully traverse each of the present §103 obviousness rejections.

Of Bissett, Ancira, and Rath, only Ancira actually teaches L-cysteine. Bissett and Rath do not teach the presently claimed L-cysteine or a salt thereof, but rather teach N-acetyl-L-cysteine and N-acetyl-cysteine, respectively, which are derivatives of L-cysteine. Therefore, Bissett and Rath cannot and do not disclose or suggest the subject matter of the presently rejected claims.

The examiner’s position with respect to Bissett and Rath seems to be that “it would be obvious to a person of ordinary skill in the art at the time the invention was made to have used L Cysteine, which would possess the same properties as a derivative.”

Applicants respectfully disagree.

The examiner’s conclusion that the presently claimed L-cysteine and the taught N-acetyl-L-cysteine and N-acetyl-cysteine “would possess the same properties” is improper. L-cysteine and N-acetyl-L-cysteine have the following structural formulas:



Thus, N-acetyl-L-cysteine and N-acetyl-cysteine are not homologs of L-cysteine. Therefore, there is no presumed expectation that the taught N-acetyl-L-cysteine and N-acetyl-cysteine "would possess the same properties" as the presently claimed L-cysteine.

Additionally, the examiner has not identified in either of (i) the disclosures of any of the presently applied prior art documents and/or (ii) the knowledge generally available to one of ordinary skill in the present art, a teaching that N-acetyl-L-cysteine and N-acetyl-cysteine would be expected to have the same properties as the presently claimed L-cysteine.

Further, N-acetyl-L-cysteine and N-acetyl-cysteine are used as a mucolytic agent based on their functions to reduce the viscosity of mucus and facilitate its removal, and they are also known as antidotes for acetaminophen poisoning (*cf.* the attached reference: DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 30th edition, p. 14, left column). On the other hand, such uses are not known for L-cysteine (*cf.* the attached reference: DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 30th edition, p. 465, left column). Accordingly, it is apparent that L-cysteine does not have the same properties (pharmacological effects) as N-acetyl-L-cysteine and N-acetyl-cysteine. Accordingly, even if Bissett discloses tranexamic acid and N-acetyl-L-cysteine, it is not obvious from the reference that a composition in which tranexamic acid and N-acetyl-L-cysteine are combined has an excellent effect of preventing pigmentations.

With respect to the §103 obviousness rejection based on Ancira, the fact that the specifically claimed combination of (i) tranexamic acid or a salt thereof and (ii) L-cysteine or a salt thereof may be encompassed by the teaching at paragraph [0034] of Ancira is not sufficient, by itself, to establish a *prima facie* case of obviousness. The burden is still on the examiner to

show that some motivation to select the specifically claimed combination of (i) tranexamic acid or a salt thereof and (ii) L-cysteine or a salt thereof is taught by Ancira. It is Applicants' position that the examiner has not identified any motivation to select the specifically claimed combination of (i) tranexamic acid or a salt thereof and (ii) L-cysteine or a salt thereof.

Also, it may be that Bissett discloses tranexamic acid and N-acetyl-L-cysteine as the components for controlling skin conditions. It may be that Ancira discloses L-cysteine as a melanin inhibitor. It may be that Rath discloses that tranexamic acid and N-acetyl-L-cysteine are effective for extracellular matrix degeneration such as cancer.

However, none of these references teaches a combination of tranexamic acid and N-acetyl-L-cysteine for preventing/treating pigmentations. In addition, although each of tranexamic acid, L-ascorbic acid, L-cysteine, etc. may be known as an agent for preventing/treating pigmentations as a single agent (*cf.* the section of Background Art in the present specification), combinations of agents do not always exhibit excellent effects to prevent pigmentations. As a matter of fact, Table 1 of the present specification shows the following:

- L-ascorbic acid- and L-cysteine-administered group (sample (7)) did not exhibit a significant effect to inhibit pigmentations in comparison with the control (sample (I));
- L-ascorbic acid- and L-cysteine-administered group (sample (7)) did not exhibit an effect to inhibit pigmentations in comparison with L-ascorbic acid single administered group (sample (4)) and with L-cysteine single-administered group (sample (3)) and rather exhibited an effect to accelerate pigmentations; and
- Combination of tranexamic acid and L-cysteine (sample (6)) and combination of tranexamic acid, L-cysteine and L-ascorbic acid exhibited excellent effects to inhibit pigmentations. Combination of tranexamic acid and L-cysteine (sample (6)) and combination of tranexamic acid, L-cysteine and L-ascorbic acid (sample (8)) exhibited excellent effects to inhibit pigmentations.

The excellent effects highlighted above and established in the specification were discovered for the first time by the present inventors in the present application and are

completely unexpected from the examiner's applied art. Therefore, the presently claimed subject matter is not obvious under §103 to one skilled in the art.

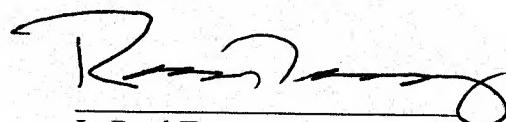
Reconsideration and withdrawal of the present §103 obviousness rejections is requested.

IV. CONCLUSION

Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the examiner feels may be best resolved through a personal or telephone interview, the examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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